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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/851,410	05/07/2001	Gregory R. Reyes	4600-0183.26	2902

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PERKINS COIE LLP
P.O. BOX 2168
MENLO PARK, CA 94026

EXAMINER	
MOSHER, MARY	
ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 10/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/851,410	REYES ET AL.	
	Examiner	Art Unit	
	Mary E. Mosher, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 July 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *42-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *42-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

Claims 43-51, 56, 57-61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claims 42, 45, 54 are drawn to an isolated polypeptide, which is a compound. Dependent claims 43, 46, 50, 56, and 60 recite "wherein said peptide further comprises an adjuvant"; is the intent really to claim a chimeric protein with HEV sequence fused to a (proteinaceous?) adjuvant? Or is the intent really to claim a composition comprising the isolated polypeptide and an adjuvant? Claims 44, 46, 51, 57, and 61 similarly add composition limitations to a compound claim in stating "said peptide comprises a preparation." Furthermore, these claims recite an intended use "for use as a vaccine," but do not make any positive statement on the actual components of the compound (or composition) that is the subject matter of these claims.

Claim 45 is indefinite in reciting "a nucleic acid homologous a nucleic acid." The recitation seems to have a typo, and in addition the claim is indefinite in failing to define the extent of changes that are encompassed by the term "homologous." The specification on page 46 defines "homologous" as capable of hybridizing under conditions described in a standard reference book. The examiner has consulted the cited reference, and determined that the cited pages deal with methods of attaching DNA to filters, not hybridization conditions. Furthermore, the subsequent pages in the book, which do deal with hybridization conditions, state that choice of hybridization

conditions "depends to a large extent on personal preference." Therefore "homologous" as defined in the specification does not set any definite metes and bounds on the claimed subject matter.

In claim 48, is "said nucleic acid" the nucleic acid in the expression vector or the nucleic acid which is the reference point for homology determination?

Claim 49 is confusing in reciting "at most about 25-30% base pair mismatches." "At most" indicates an upper limit, but "25-30%" indicates a closed range; which is intended?. Also, "at most about" is confusing. For example, 31% mismatches is "about 30%" but exceeds "at most 30%;" would 31% mismatches be included or excluded from the claim?

Claim 58-61 are confusing in using both open "comprising" and closed "about 100 to about 300 amino acids" (or base pairs). Do the claims include or exclude peptides with, say, 400 amino acids of HEV ORF2?

Claims 44-61 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for isolated peptides which are specifically immunoreactive with antibodies present in individuals infected with hepatitis E virus (HEV), and for immunogenic compositions comprising the same, the specification does not reasonably provide enablement for all the peptide fragments and variants encompassed by the claims or for the full scope of protective vaccines. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The specification discloses an enabling diagnostic use for

peptides which react with antibodies from infected individuals, but does not teach how to use peptides which lack this functionality. Furthermore, the specification generally asserts that the peptides can be used in vaccines, but provides no evidence that any of the claimed peptides are capable of inducing an immune response protective against disease. Aggarwal et al (2000), cited previously, indicates that HEV immunogens are still not accepted as effective in preventing infection, many years after applicant's effective filing date. Considering the limited disclosure in the specification, the absence of working examples, and the unpredictability of a protective immune response, it is concluded that undue experimentation would be required to make and use protective vaccines, as claimed.

Double Patenting

Claims 42, 45, 48, 49, 52-55, 58-59 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5-10, 24-29 of U.S. Patent No. 5824649. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims encompass previously patented HEV Orf2 proteins and fragments.

Claims 54, 55, 58, 59 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6214970 or 6291641 or 5770689, or claims 1, 3, 4 of U.S. Patent No. 5885768. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant fragment claims encompass the previously patented fragments.

Claims 43, 44, 46, 47, 50, 51, 56, 57, 60, 61 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 5741490. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims encompass the previously patented compositions.

Claims 56, 57, 60, 61 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of copending Application No. 10/165868. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant fragment product claims encompass the copending fragment product claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 43, 44, 46, 47, 50, 51, 56, 57, 60, 61 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 22, 23 of copending Application No. 09/769066. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant peptide and fragment composition claims encompass the copending vaccine composition claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906. The examiner can normally be reached on M-T and alternate F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

10/14/04

MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1800 1600